DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

December 19, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W. Phillip Conklin, President
Conklin Enterprises, Inc.
P.O. Box 972
Murrells Inlet, SC 29576

Warning Letter
02-ATL-16

Dear Mr. Conklin:

On November 23, 24, and 27, 2001, an investigator from the Food and Drug Administration (FDA), Nancy E. Ford, conducted an inspection of your plant located at 3476 Highway 17 Business, Murrells Inlet, South Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh histamine-producing fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The HACCP deviations of concern are as follows:

1. Our review of your firm's HACCP plan for histamine-producing fish reveals that it is deficient and fails to meet requirements under 21 CFR 123.6(c) as follows:

   a. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your HACCP plan does not list a critical limit for the sensory examination at the "Receiving" (as a primary processor) critical control point (CCP) even though it lists sensory examination as one of the preventive measures used by your firm to address the histamine formation hazard.

      In addition, your critical limit at the "Storage" CCP, i.e. "iced," is not adequate to control the food safety hazard of histamine formation. It should describe what is an adequate amount of ice. For example, "Product completely covered in ice throughout storage."

b. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan does not list the monitoring procedure and frequency for the sensory examination for decomposition at the "Receiving" CCP to control the histamine formation hazard.

c. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan at the "Storage" CCP is not adequate to control the hazard of histamine formation. Specifically, re-icing product when the ice has melted or is not sufficient to cover the fish may not be enough to prevent the histamine formation hazard. The affected product must be evaluated by a trained individual to determine its acceptability for distribution.

We suggest that you refer to Chapter 7 of the *Fish & Fisheries Products Hazards & Controls Guidance, third edition* (copy enclosed), for guidance in establishing critical limits and monitoring procedures for controlling the histamine hazard in the fish you process.

2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of checking the internal temperature of incoming histamine-producing fish, reviewing the harvest vessel records, or performing a sensory examination for decomposition, for each lot of histamine producing fish received. Moreover, there were no HACCP monitoring records available for the "Receiving" critical control point for shipments of histamine fish received between 7/18/01 and 11/21/01.

   In addition, the presence of ice on histamine-producing fish received from other seafood processors has not being documented.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure